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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/036,063

12/26/2001

Audrey Goddard

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04/16/2007

KNOBBE, MARTENS, OLSON & BEAR, LLP

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EXAMINER

KOLKER, DANIEL E

ART UNIT

PAPER NUMBER

1649

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/036,063

Applicant(s)

GODDARD ET AL.

Examiner

Daniel Kolker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-26, 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. The remarks and declaration filed 22 January 2007 have been entered. No claims have been amended. Claims 22 – 26 and 28 – 30 are pending and under examination.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Continued Examination Under 37 CFR 1.114***

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 January 2007 has been entered.

### ***Maintained Rejections***

#### ***Claim Rejections - 35 USC § 102***

4. Claims 22 – 25 and 28 – 29 stand rejected under 35 U.S.C. 102(a) as being anticipated by Ruben (WO 99/58660, of record, "Ruben I").

This rejection stands for the reasons of record and explained in further detail herein. Briefly, Ruben I was published less than a year before the earliest effective filing date of this application and thus qualifies as prior art under 35 USC 102(a). As set forth on page 2 of the office action mailed 17 March 2005, priority is not granted to the provisional application. The provisional application does not disclose how to use the claimed antibodies, as it does not disclose the results of the kidney mesangial cell proliferation assay. Ruben I teaches a protein 99.6% identical to applicant's SEQ ID NO:57 and teaches antibodies to same.

Applicant argues that the declaration submitted 22 January 2007 and the provisional application, taken together, are sufficient to antedate the Ruben I reference. Applicant argues that the written description guidelines, particularly Example 16, provide support for the argument that demonstrating possession of the protein is sufficient to demonstrate possession of the antibody. Applicant also argues that according to the Stempel doctrine, an applicant need not show that he or she was in possession of the full scope of the claimed invention but rather need only show as much as the reference to be overcome shows.

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Applicant's arguments have been fully considered but they are not persuasive. The declaration filed on 22 January 2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the Ruben I reference. The declaration shows reduction to practice of the protein of SEQ ID NO:57 and the nucleic acid encoding it. The declaration does not show possession of the antibodies, which are now claimed. In contrast, the reference (Ruben I) teaches antibodies. Therefore, the declaration does not teach at least as much as the reference. The reference teaches antibodies, and the declaration does not provide evidence of possession of the antibodies. On p. 6 (final paragraph) of the remarks filed 22 January 2007, applicant states that Ruben was not in possession of the antibodies, even though they appear in the publication, but rather merely contemplated their production and existence. This is applicant's own conclusion, not a statement of fact. The examiner has no reason to doubt what is set forth in the Ruben I publication, even though applicant characterizes it as mere contemplation. The publication by Ruben states that the invention includes antibodies. The declaration submitted 22 January 2007 does not provide evidence of possession of antibodies. Thus the declaration does not teach at least as much as the reference.

With respect to the argument that the written description guidelines provide support for the assertion that possession of a protein constitutes evidence of possession of antibodies which bind to the protein, applicant's arguments are not persuasive. The examiner has carefully reviewed Example 16, available on the internet at <http://www.uspto.gov/web/menu/written.pdf>. In Example 16, the hypothetical specification teaches a protein and contemplates but does not reduce to practice the antibodies that bind to it. Unlike applicant's provisional application, the hypothetical specification discloses how to use the protein. The hypothetical specification discloses how to make antibodies to that protein, and how to use them (i.e. for detection of HIV). However, the issue here is not one of description of the invention but rather of whether or not applicant was in possession of the invention before the effective date of Ruben I.

The examiner does not doubt that the physical structure of the antibodies is described sufficiently in the provisional application. A review of the prosecution history of this application reveals that there never was a written description rejection over the antibody claims. However, whether or not a product has been described is a separate issue from whether or not applicant was in possession of that product. There is no evidence of record that applicant was actually in possession of the claimed antibodies, although he was in possession of the protein to which the antibodies bind, as evidenced by the declaration filed 22 January 2007. While the provisional

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application *describes* the antibodies now claimed, priority has been denied because it does not disclose how to use the antibodies and thus fails to conform to the "make and use" requirements of 35 USC 112, first paragraph.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/130359, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The provisional application fails to teach how to use the antibodies now claimed, as it fails to teach how to use the protein to which they bind.

For the reasons above, the rejection of claims 22 – 25 and 28 – 30 over Ruben I stands.

5. Claims 22 – 25 and 28 – 29 stand rejected under 35 U.S.C. 102(e) as being anticipated by Ruben (U.S. Patent Application Publication 2003/0100051, of record, "Ruben II").

This rejection stands for the reasons of record. The Ruben II reference is the same disclosure as the Ruben I reference; it appears the only difference is that the Ruben I reference is a WIPO Publication whereas the Ruben II reference is a U.S. Patent Application Publication. The examiner believes that the facts have been addressed in previous office actions and in the discussion of Ruben I, above, and thus for the sake of brevity will not be reiterated.

However, even if it were later found that the declaration filed 22 January 2007 under 37 CFR 1.131 were sufficient to overcome the Ruben I reference, the same declaration would be ineffective to overcome the Ruben II reference. The Ruben II reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention. See specifically Ruben II, claim 13. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or

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declaration under 37 CFR 1.130. See MPEP § 718. Thus the rejection of claims 22 – 25 and 28 – 29 stands for the reasons of record as well as those explained above.

***Claim Rejections - 35 USC § 103***

6. Claims 22 – 26 and 28 – 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruben (WO 99/58660) in view of Holmes (Current Protocols in Immunology, of record).

This rejection stands for the reasons previously made of record. In the remarks filed 22 January 2007, applicant did not traverse the examiner's determination that the claims are obvious over the teachings of the two references, but rather argued that Ruben I does not qualify as prior art under 35 USC § 102 and thus is not available as prior art under § 103. As explained in paragraph number 4 above, Ruben I anticipates claims 22 – 25 and 28 – 29; therefore the reference qualifies as prior art under §§ 102 and 103 and the rejection stands.

7. Claims 22 – 26 and 28 – 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruben (US Patent Application Publication 2003/0100051) in view of Holmes (Current Protocols in Immunology, cited in previous office action).

This rejection stands for the reasons previously made of record. In the remarks filed 22 January 2007, applicant did not traverse the examiner's determination that the claims are obvious over the teachings of the two references, but rather argued that Ruben II does not qualify as prior art under 35 USC § 102 and thus is not available as prior art under § 103. As explained in paragraph number 5 above, Ruben II anticipates claims 22 – 25 and 28 – 29; therefore the reference qualifies as prior art under §§ 102 and 103 and the rejection stands.

***Conclusion***

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DK

Daniel E. Kolker, Ph.D.

April 12, 2007



ROBERT C. HAYES, PH.D.  
PRIMARY EXAMINER